

REMARKS

Applicants gratefully acknowledge withdrawal of the previous grounds of rejection. The claims are rejected as obvious on new grounds discussed below. Applicants present the attached Declaration under 37 C.F.R. § 1.132 of Masatake Dairaku (hereafter Dairaku Declaration) and arguments below responsive to the new grounds of rejection.

Rejection under 35 U.S.C. § 103(a)

Claims 1 and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ninomiya, et al. (US 5932235, previously cited) in view of Friedman, et al. (Oncologist 5: 136-143, 2000), Nguyen, et al. (Annals of Oncology 15: 383-388, 2004), David, et al. (Glycerol: A Jack of All Trades), Bowen et al (US 2004/0057908) and Quercia, et al.(previously cited).

The presently claimed invention is directed to a specific preferred embodiment comprising “granisetron hydrochloride, a carrageenan, locust bean gum, sodium polyacrylate, D-sorbitol, glycerin, and water, wherein the carrageenan is kappa (κ)-carrageenan and/or iota (ι)-carrageenan, and wherein the composition has a pH of 7 or less” (present claim 1).

As correctly summarized by the Examiner, Ninomiya, et al. teach compositions comprising κ -carrageenan, locust bean gum, sodium polyacrylate, D-sorbitol, and water. Ninomiya, et al. do NOT teach granisetron HCl, glycerin and where the pH is 7 or less as claimed.

As previously discussed, Granisetron hydrochloride has a tendency to foam when blended with carrageenan, locust bean gum and sodium polyacrylate. Upon inclusion of D-sorbitol and glycerin in a composition comprising granisetron hydrochloride, the specified carrageenans, locust bean gum and sodium polyacrylate, the foaming problem is resolved without adversely affecting the appearance of the final product.

Ninomiya, et al. do not teach compositions comprising Granisetron HCl and do not address the foaming problem encountered when combining Granisetron HCl with κ -carrageenan, locust bean gum, and sodium polyacrylate.

As mentioned above, Ninomiya, et al. do not exemplify Granisetron HCl. While the Examiner points out that Ninomiya, et al. teach that “any medically effective components may be used” (Office Action, page 4, citing Ninomiya, et al.), were they to combine Granisetron HCl

with the other components taught by this reference, they would have encountered the foaming problem discussed above.

Friedman, et al is cited for teaching that Granisetron HCl is used to treat nausea and vomiting during chemotherapy. Nguyen, et al. teach that dysphagia is associated with head and neck malignancies so that one with such condition, who may also be having chemotherapy and therefore needing Granisetron HCl, would seek a jellied form of the medication. However, neither Friedman, et al. nor Nguyen, et al. teach the jellied form of Granisetron HCl of Applicants' claimed composition. Furthermore, these references do not address the technical problem outlined above of foaming during the formulation of the jellied Granisetron HCl product.

The inclusion of glycerin in the claimed composition of Applicants resolves the foaming problem. This result was unexpected and could not have been predicted from the prior art as shown by the Dairaku Declaration and discussed below.

Applicants present the attached Dairaku Declaration which compares the anti-foaming effectiveness of glycerin, according to the claimed invention, with a second polyalcohol, propylene glycol.

As can be seen by the Table in the Dairaku Declaration, propylene glycol did not alleviate the foaming problem. Results obtained using propylene glycol (columns 5-7) were about the same as no additive (column 1). Only columns 2-4, in which glycerin was added to the composition, show reduced foaming.

This result could not have been predicted from the prior art as none of the prior art references teach any effect of glycerin as a defoaming agent. Accordingly, one of ordinary skill in the art faced with the foaming problem caused by the combination of Granisetron HCl and D-sorbitol, would not turn to glycerin to solve the foaming problem.

Furthermore, the effect on foaming is quite specific to glycerin as other polyalcohols (propylene glycol) did not show the same effect. This was unexpected. As propylene glycol is chemically similar to glycerin, one of ordinary skill in the art would have expected the two compounds to have similar effects. However, the experimental results showed that the two compounds have very different effects on foaming in the granisetron HCl/D-sorbitol composition.

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David, et al. and Bowen, et al. are cited to teach the use of glycerin to prevent drying out of pharmaceutical products. The Office Action asserts that one of ordinary skill in the art would add glycerin to the composition produced from the combination of references above as a humectant in view of David, et al. and Bowen, et al.

However, as stated in the Dairaku Declaration, the jelled composition must include sorbitol. Sorbitol is a well known humectant. See for example the attached description from Wikipedia (Attachment). Accordingly, there would be no apparent reason to add an additional humectant as the composition already necessarily includes sorbitol which is an effective humectant. Neither David, et al. nor Bowen, et al. teach anything regarding the use of glycerin as a defoaming agent. The combination of references provides no reason to add Granisetron HCl and glycerin to the compositions taught by Ninomiya, et al.

Accordingly, while the components of Applicants' claimed medicine for oral administration were known, the combination of Granisetron HCl with D-sorbitol and glycerin was not known. Furthermore, the ability of glycerin to solve the foaming problem which is the result of combining Granisetron HCl and D-sorbitol was unexpected and could not be predicted from the prior art.

In view of the Dairaku Declaration and the arguments above, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claim 2 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ninomiya, et al. (US 5932235, previously cited) in view of Friedman, et al. (Oncologist 5: 136-143, 2000), Nguyen, et al. (Annals of Oncology 15: 383-388, 2004), David, et al. (Glycerol: A Jack of All Trades), Bowen et al (US 2004/0057908) and Quercia, et al.(previously cited) as applied to claim 1 above, in further view of Hai (previously cited) and Shushin, et al. (Russian Chem Bull 43: 1646-1650, 1994).

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to combine a reductant as taught by Hai, et al. and Shushin, et al. with the composition as taught by Ninomiya, et al. Friedman, et al. Nguyen, et al. David, et al. (Glycerol: A Jack of All Trades), Bowen et al and Quercia, et al.. However, since claim 2 depends from claim 1, which is neither

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taught nor suggested by the combination of references applied against claim 1 as discussed above, the invention defined in claim 2 is also patentably distinguished from the references, alone or in combination. Applicants respectfully request the withdrawal of the rejection.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of the Dairaku Declaration and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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